



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,350	12/03/2003	Kiamars Hajizadeh	3873 P 040	5453
<div>7590      03/28/2007</div> <div>ROGER H. STEIN WALLENSTEIN WAGNER &amp; ROCKEY, LTD. 53rd Floor 311 South Wacker Chicago, IL 60606-6622</div>			<div>EXAMINER</div> <div>SINES, BRIAN J</div>	
			<div>ART UNIT</div> <div>1743</div>	<div>PAPER NUMBER</div>
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/28/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/727,350

Applicant(s)

HAJIZADEH ET AL.

Examiner

Brian J. Sines

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/3/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION*****Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, with respect to claim 8, the hinge feature must be shown and labeled or the feature(s) canceled from the claim(s). With respect to claim 10, the means for receiving a fluid sample that is positioned between each of the pair of electrodes must be shown and labeled or the feature(s) canceled from the claim(s). With respect to claim 12, the vent located between each of the paired electrodes must be shown and labeled or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 10 – 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps.

See MPEP § 2172.01. The omitted steps are:

Regarding claim 8, it is unclear as to how a hinge is formed during the molding step in a space between each of the paired electrodes as claimed. Is the hinge positioned at the fluid sample receiving end 16 of each sensor 10? In addition, this hinge feature does not appear to be clearly shown in the accompanying drawings.

Regarding claim 10, it is unclear as to how a means for receiving fluid sample is formed during the molding step in a space between each of the paired electrodes as claimed. Is the means for receiving fluid sample positioned at the fluid sample receiving end 16 of each sensor 10? In addition, this feature does not appear to be clearly shown in the accompanying drawings.

Regarding claim 12, it is unclear as to how a vent is formed between each paired electrodes during the molding step as claimed. In addition, this feature does not appear to be clearly shown in the accompanying drawings.

Claim 11 recites the limitation "means for receiving the fluid sample" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

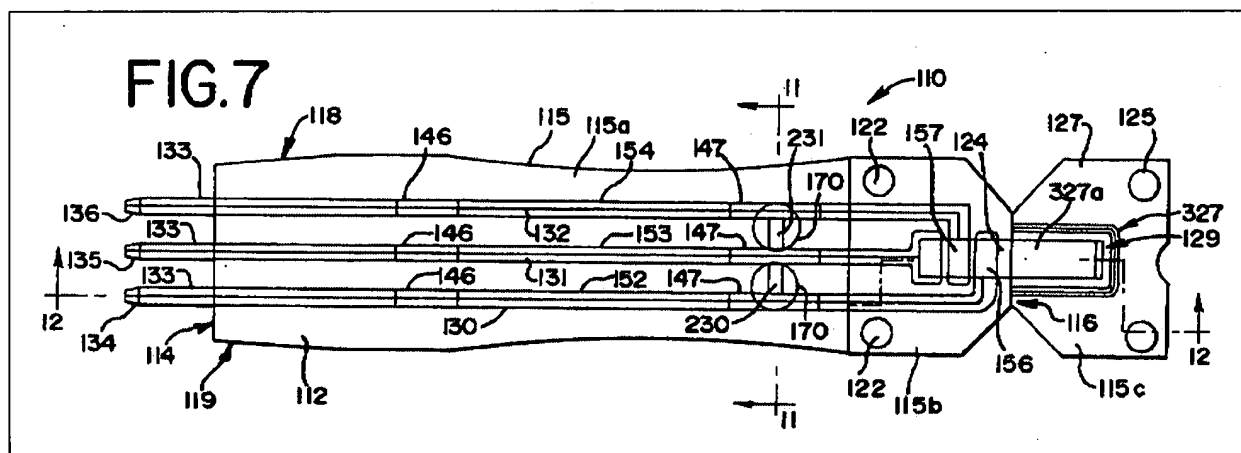
Claims 1, 2, 4 – 7, 9, 11, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Rappin et al. (U.S. 6,576,102) (“Rappin”).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Regarding claims 1 and 14, Rappin anticipates the claimed method of molding a testing device. Rappin teaches the step of positioning a plurality of paired, spaced-apart conductive electrodes 130, 131, 132 in a mold (e.g., body 12, 112) for a carrier; and molding a carrier of insulative material to at least embed a portion of the electrodes in the insulative material to permit exposure of at least a portion of one electrode to a fluid sample to be treated (see col. 7, lines 1 – 30; col. 8, lines 17 – 21; figure 7). Rappin teaches that the body 12 is constructed of an electrically insulating injection moldable plastic (see col. 5, lines 19 – 24). The fluid sample receiving end 116 of the sensor 110 includes an electrochemical reaction zone 124 adjacent the

Art Unit: 1743

terminal end 116 of the body (see col. 8, lines 22 – 55). Rappin anticipates a further treatment step comprising treating at least one of the electrodes with one or more substances before or after the molding of the carrier for reacting with the fluid sample to be tested. Rappin teaches that an enzyme 156 is applied to the outer surface of the primary electrode 152 (see col. Col. 2, lines 14 – 63; 9, lines 35 – 65).



Regarding claims 2, 6 and 7, Rappin anticipates a molding step that includes molding the insulative material to at least encase or embed at least a portion of the electrodes (see, e.g., col. 4, lines 54 – 61; col. 5, lines 6 – 67; col. 9, lines 19 – 23; col. 6, lines 4 – 40; col. 10, lines 5 – 15).

Regarding claim 4, Rappin anticipates the step of using electrode leads are formed by stamping out a specific pattern from an electrically conductive plate (see col. 4, line 62 – col. 5, line 5).

Regarding claim 5, Rappin anticipates that the electrode leads are held in place during the molding step (see, e.g., col. 7, lines 12 – 30).

Regarding claim 9, Rappin anticipates the step of end cap 27 molding and device assembly (see col. 4, lines 12 – 53; col. 7, lines 1 – 50).

Art Unit: 1743

Regarding claim 11, Rappin anticipates the incorporation of a capillary inlet or opening 28 formed in the terminal end 16 of the sensor 10 when the cap 27 is welded or folded to the body 12. Rappin also anticipates the incorporation of a vent 29 (see col. 4, lines 26 – 53; figures 1 – 6).

Regarding claim 13, Rappin anticipates the incorporation of a means for detecting the presence of an adequate amount of fluid sample between each of the paired electrodes (see, e.g., col. 2, lines 14 – 63; col. 6, lines 40 – 67).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rappin.

Regarding claim 3, Rappin does not specifically teach that the electrically conductive wires are pulled into the mold before the molding step. Though Rappin teaches that conductive leads 30, 31 and 32 are first molded into the product. Rappin teaches that the wire leads are fed

Art Unit: 1743

into the mold and placed on or between figures or apparently finger structures [not shown] projecting into the mold through openings in the mold to hold the wires in place and level during the set-up and molding process. The bottom apertures permit the fingers projecting into the mold to hold the wires in place. Once the plastic has formed and hardened, the fingers are pulled from and exit the mold through the openings (apertures 46, 48, 50) (see col. 7, lines 12 – 34). Pulling rather than feeding the wires through the mold prior to molding the sensor structure is an obvious alternative step in positioning the wires in the mold structure prior to molding. Therefore, it would have been obvious to a person of ordinary skill in the art to include a step of pulling the wires into the mold before the molding step.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

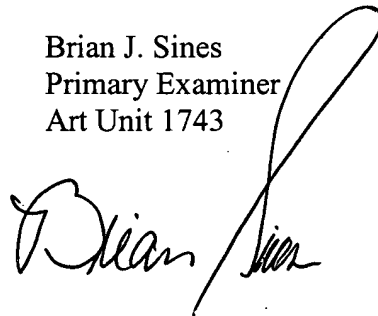
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian J. Sines  
Primary Examiner  
Art Unit 1743

A handwritten signature in black ink, appearing to read "Brian Sines", with a large, stylized loop extending from the end of the signature.